

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
21 June 2001 (21.06.2001)

PCT

(10) International Publication Number
WO 01/43641 A1

(51) International Patent Classification⁷:

A61B 8/00

(21) International Application Number:

PCT/US00/26322

(22) International Filing Date:

26 September 2000 (26.09.2000)

(72) Inventors; and

(75) Inventors/Applicants (for US only): **GILBOA, Pinhas** [IL/IL]; Zidkiyah St. 8, 34409 Haifa (IL). **ZUR, Oded** [IL/IL]; Menachem Begin St. 5/6, 42655 Natanya (IL). **ESHET, Omer** [IL/IL]; 49910 Kibbutz Einat (IL).

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

60/170,776 15 December 1999 (15.12.1999) US

(71) Applicant (for all designated States except US): **SUPER DIMENSION LTD.** [IL/IL]; P.O. Box 12294, 46733 Herzlia (IL).

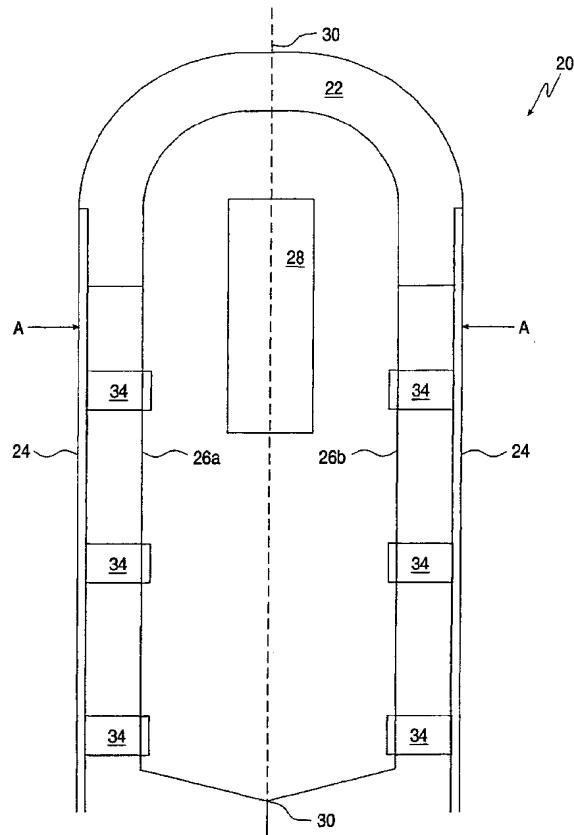
(71) Applicant (for TJ only): **FRIEDMAN, Mark, M.** [US/IL]; Alharizi St. 1, 43406 Raanana (IL).

(74) Common Representative: **FRIEDMAN, Mark, M.**; c/o Castorina, Anthony, Suite 207, 2001 Jefferson Davis Highway, Arlington, VA 22202 (IL).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

[Continued on next page]

(54) Title: DEVICE AND METHOD FOR APPLYING ENERGY TO A TARGET



(57) Abstract: A probe for applying energy to a target, and a method for its use. The probe includes a sensor [28] for determining the position of the probe, and a generator of a force field that interacts with the target to apply the energy to the target. To minimize interactions between the sensor and the force field generator, the force field generator is disposed relative to the sensor [28] so that there is a node of the force field at the sensor. For example, if the sensor [28] is at an element of symmetry of the catheter, the force field generator is disposed so that a node of the force field is coincident with that element of symmetry. The sensor is used to ensure that the probe remains in proximity to the target while the energy is applied to the target.

WO 01/43641 A1



- (84) **Designated States (regional):** ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

DEVICE AND METHOD FOR APPLYING ENERGY TO A TARGET

5 FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to a device for remote application of energy to a target and, more particularly, to a probe, such as a catheter, that includes a sensor for navigating the probe to the target and a force field generator, for depositing the energy at the target, that is configured to interfere minimally with the sensor.

10 In recent years, several intra-body navigation systems have been developed. Gilboa et al., in WO 00/10456, Ben-Haim et al., in WO 96/05768, and Acker et al., in US 5,558,091 all teach locating systems for tracking the tip of a catheter inside body cavities and blood vessels of a medical or veterinary patient. This is performed by transmitting low frequency electromagnetic waves into the patient's body, 15 incorporating a miniature sensor at the tip of the catheter to measure the field components and calculating the position and orientation of the sensor relative to an external reference frame of coordinates. Martinelli et al., in US 4,821,731, Pfeiler et al., in US 5,042,486, and Smith et al., in US 5,515,853, teach localization systems based on ultrasonic waves, in which several ultrasound transmitters are placed on the 20 surface of the patient's body and an ultrasound receiver is placed at the tip of the catheter. By measuring the propagation time, the distances between the transmitters and the tip are determined, and the position of the tip is determined by triangulation. Wittkampf, in US 5,697,377, describes a localization system in which three pairs of electrodes are attached to the surface of the patient's body to form three identifiable, 25 mutually orthogonal electrical potentials through the body. An electrode incorporated

at the tip of the catheter senses the local electrical potential. From this electrical potential, the position of the catheter electrode is determined.

Intra-body medical and veterinary therapeutic and diagnostic applications have been developed that rely on these navigation systems. For example, Ben-Haim, in US 5,391,199, and Gilboa et al., in WO 00/16684, describe procedures for locating a steerable ablation catheter that is used to treat arrhythmia by ablating a portion of the endocardium using RF current signals. Figure 1 shows an axial cross section of the distal end of one such catheter **10**. The body of catheter **10** is a flexible, substantially cylindrical housing **14**. A metal electrode **12** is mounted at the tip of catheter **10**. An external RF generator is connected to electrode **12** via a conductor **16** that runs along the length of housing **14**. Electrode **12** is secured in contact with the portion of the endocardium to be ablated. That portion of the endocardium then forms the return portion of an electrical circuit. By applying a RF current to conductor **16**, the tissue through which the current is conducted is heated and ablated. An electromagnetic sensor **18**, for determining the position and orientation of electrode **12**, also is incorporated in the tip of catheter **10**, in close proximity to conductor **16**. It is vital that the position and orientation measurements, performed using sensor **18** during the application of the RF signal, be accurate. However, the current conducted via conductor **16** also induces an electromagnetic field. This additional field is sensed by sensor **18**, resulting in a strong jitter of the determined position and orientation. Electronic filtering of the signal from sensor **18** increases the signal-to-noise ratio but delays the response of the navigation system. A similar problem arises when using ultrasonic localization and transmitting ultrasound power while performing ablation or similar procedures such as lithotripsy.

There is thus a widely recognized need for, and it would be highly advantageous to have, a catheter, for the remote effectuation of therapeutic procedures, such as ablation, that apply energy to a target, in which the application of the energy does not interfere with the navigation and localization of the catheter.

5

SUMMARY OF THE INVENTION

According to the present invention there is provided a probe, including: (a) a sensor for determining a position of the probe; and (b) a force field generator, disposed relative to the sensor so that there is a node of the force field substantially at 10 the sensor.

According to the present invention there is provided a method for applying energy to a target, including the steps of: (a) providing a probe including: (i) a sensor for determining a position of the probe, and (ii) a force field generator, disposed relative to the sensor so that there is a node of the force field substantially at the 15 sensor; (b) placing the probe in proximity to the target, with reference to at least one determination of the position of the probe made using the sensor; and (c) generating the force field, using the generator, the energy being applied to the target by an interaction of the force field with the target.

According to the present invention there is provided a method for applying 20 energy to a target, including the steps of: (a) providing a probe including: (i) a sensor for determining a position of the probe, and (ii) a force field generator including a plurality of elements; (b) placing the probe in proximity to the target, with reference to at least one determination of the position of the probe made using the sensor; and (c) generating the force field, using the elements in a manner that produces a node of the

force field substantially at the sensor, the energy being applied to the target by an interaction of the force field with the target.

According to the present invention there is provided a probe including: (a) a housing; and (b) a force field generator, disposed so that there is a node of the force at least partially within the housing.

According to the present invention there is provided a method for applying energy to a target, including the steps of: (a) providing a probe including: a force field generator; (b) placing the probe in proximity to the target; and (c) generating the force field, using the generator, in a manner that applies the energy to the target, the force field having a node at least partially within the probe.

According to the present invention there is provided a probe, including: (a) a force field generator; and (b) a sensor for producing a signal, the signal being subject to perturbation by the force field, the force field generator being disposed so as to minimize the perturbation.

According to the present invention there is provided a method for applying energy to a target, including the steps of: (a) providing a probe including: (i) a force field generator, and (ii) a sensor for producing a signal, the signal being subject to perturbation by the force field, the force field generator being disposed so as to minimize the perturbation; (b) placing the probe in proximity to the target; and (c) generating the force field, using the generator, in a manner that applies the energy to the target.

In the present context, a "probe" is to be understood as any device for remote application of energy to a target. Typically, the "probe" of the present invention is a catheter for effecting a medical or veterinary therapeutic procedure; but the scope of

the present invention includes any such procedure that must be effected remotely, for example, real-time repair of a nuclear reactor.

The probe includes a sensor for determining the position of the probe, and a force field generator for generating the force field that interacts with the target to 5 deposit the required energy in the target. Because the force field is liable to perturb the signal from the sensor that is representative of the position of the probe, the force field generator is disposed relative to the sensor so as to minimize this perturbation. Preferably, the force field generator is disposed relative to the sensor so that there is a node of the force field substantially at the sensor. A "node" of the force field is a 10 point, line or surface at or along which the amplitude of the force is zero while the generator is operated. The "disposition" of the force field generator that places a node of the force field at the sensor is to be understood to include either a suitable geometric placement of the force field generator relative to the sensor, or a suitable mode of operation of the force field generator, or a suitable combination thereof.

15 The scope of the present invention includes both oscillatory force fields and static force fields. Examples of oscillatory force fields include electromagnetic and acoustic force fields. Examples of static force fields include DC electrical and magnetic force fields.

20 Preferably, the sensor is rigidly attached to the probe housing at an element of symmetry of the housing, and the force field generator is disposed symmetrically with respect to the sensor by being rigidly attached to the housing in a manner which is symmetrical with respect to the element of symmetry, so that a node of the force field is substantially coincident with the element of symmetry. For example, the force field

generator may include a plurality of elements that are disposed symmetrically with respect to the element of symmetry and with respect to the sensor.

With the force field generator so disposed relative to the sensor, the operation of the force field generator interferes minimally with navigation using the sensor.

- 5 Using signals from the sensor as taught in the prior art to determine the position of the probe, the probe is placed in proximity to the target. With the probe in proximity to the target, the force field generator is operated to apply energy to the target. Further signals from the sensor are used to determine the position of the probe while the energy is applied to the target, for the purpose of maintaining the probe in proximity
- 10 to the target while the energy is applied to the target.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

15 FIG. 1 is an axial cross section of a prior art catheter;

FIG. 2 is an axial cross section of a catheter of the present invention that is used to apply RF energy to a target;

FIG. 3 is a transverse cross section of the catheter of FIG. 2;

FIG. 4 is a transverse cross section of a variant of the catheter of FIGs. 2 and 3;

20 FIG. 5 is an axial cross section of a catheter of the present invention that is used to apply ultrasound energy to a target;

FIG. 6 is an amplitude contour plot for acoustic signals generated by the catheter of FIG. 5.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of a probe, such as a catheter, which can be used to apply energy remotely to a target. Specifically, the probe of the present invention is configured so that the application of energy to the target interferes minimally with the 5 navigation of the probe.

The principles and operation of a probe according to the present invention may be better understood with reference to the drawings and the accompanying description.

There are various medical treatments which include localized application of 10 energy to a target. The energy may be either carried to the target via a probe, such as a catheter, or generated at the tip of the probe in close proximity to the target. If the energy is associated with a field, this field may disturb a sensor in the probe that is used to determine the position of the probe relative to the target. The basic concept of 15 the present invention is that if this field is a force field, *i.e.*, a vector field, then the effect of this field on the sensor may be canceled at the probe by intentionally inducing a second field that adds vectorially to the first field at the location of the sensor to cancel the first field there.

One important class of such fields is that of oscillatory fields that carry signals 20 by wave propagation. For example, in some medical treatments, the energy is applied to the target by a coherent wave such as an RF wave, an optical wave produced by a laser, or an ultrasonic acoustic wave. In such a case, the canceling field is induced as a second wave of the same frequency as the first wave, but with a phase shift, relative to the first wave, that cancels the signals, that are carried on the first wave, at the sensor. In general, if a probe includes both a sensor for determining the position of

the probe and a mechanism for inducing a therapeutic signal, and that therapeutic signal interferes with the proper functioning of the sensor, a secondary signal is induced that cancels the primary therapeutic signal at the sensor.

Referring again to the drawings, Figure 2 is an axial cross section of the distal 5 end of a catheter **20** of the present invention, and Figure 3 is a transverse cross section of catheter **20** along cut A-A. As in prior art catheter **10**, the body of catheter **20** is a flexible, substantially cylindrical housing **24**. A metal electrode **22**, similar to electrode **12**, is mounted at the tip of catheter **20**. An electromagnetic sensor **28**, similar in structure and purpose to sensor **18**, is incorporated in the tip of catheter **20**, 10 aligned along rotational axis **30** of cylindrical housing **24**. The difference between catheter **10** and catheter **20** is that catheter **20** has two wires **26a** and **26b**, on opposite sides of axis **30**, for carrying RF current signals to electrode **22**. Wires **26a** and **26b** merge at a junction **32** that is sufficiently far from sensor **28** that RF current flowing in 15 the portion of catheter **20** that is proximal to junction **32** does not affect sensor **28** adversely.

Wires **26a** and **26b** are parallel to rotational axis **30** of cylindrical housing **24**, and equidistant from rotational axis **30**. In Figure 3, dashed lines **38a** indicate some of the magnetic lines of flux induced by the flow of electrical current in wire **26a**, and dashed lines **38b** indicate some of the magnetic lines of flux induced by the flow of 20 electrical current in wire **26b**. Arrowheads **40** indicate the direction of the associated magnetic force field, when the electrical currents are directed upwards relative to the plane of Figure 3. By symmetry, if the two currents are equal, the two fields cancel each other at axis **30**. As a result, the total magnetic field induced in catheter **20** by wires **26a** and **26b** has a nodal line along axis **30**.

Wires **26** are held in place by projections **34** from housing **24**. Similarly, sensor **28** is held in place by a projection **36** that spans housing **24**. Because sensor **28** is located at a nodal line of the total magnetic field induced by wires **26**, the disturbance by this field to the positioning signals produced by sensor **28** is negligible.

5 The “disposition” of wires **26**, that achieves the results of negligible influence on sensor **28**, has both a geometric component and an operational component. The geometric component is the siting of wires **26** parallel to, equidistant from and on opposite sides of axis **30**. The operational component is the imposition of equal RF currents in wires **26**.

10 It will be appreciated that the same effect may be achieved using more than two wires **26**, as long as those wires are parallel to axis **30**, equidistant from axis **30**, and spaced at equal azimuthal spacings around axis **30**. Figure 4 shows, in transverse cross section, the limiting case of a catheter **50**, having a cylindrical housing **54** and a sensor **58** located on rotational axis **60** of housing **54**, in which RF current is carried to 15 an electrode (not shown) at the tip of catheter **50** via a conducting nonmagnetic hollow cylinder **56** that is concentric with axis **60**. Cylinder **56** and sensor **58** are held in place by projections **64** and **66** from housing **54**.

It may not be practical to place wires **26** symmetrically around axis **30**. In such a case, the “disposition” of wires **26** includes the selection of (generally unequal) currents to be carried by wires **26** that produce a node of the magnetic field at sensor 20 **28**.

Figure 5 is an axial cross-section of the distal end of a catheter **70** of the present invention for transmitting high-power acoustic waves in a medical or veterinary procedure such as ablation of heart tissue, drilling microchannels in heart

muscle tissue, or disintegrating a kidney stone. Catheter **70** is based on a flexible, substantially cylindrical housing **72** that terminates in a tip **80**. Dashed line **74** indicates a plane of reflectional symmetry of housing **72**. Note that plane of symmetry **74** passes through tip **80**. Rigidly attached to housing **72**, on opposite sides of plane **5** of symmetry **74** and equidistant from plane of symmetry **74**, are two ultrasound transmitters **76**. Rigidly attached to housing **72** at tip **80** is an ultrasound receiver **78** that serves as a position sensor for catheter **70**, as described in Martinelli et al., Pfeiler et al. and Smith et al.

Figure 6 is a conceptual amplitude contour plot, in the plane of Figure 5, for **10** acoustic signals generated by transmitters **76** when transmitter **76** are 180 degrees out of phase. Dashed lines **82** indicate amplitude maxima. Along plane of symmetry **74**, the amplitude vanishes, indicating that plane of symmetry **74** is a nodal plane of the acoustic force field generated by transmitters **76**. Note that in this case, the “disposition” of transmitters **76**, that creates a nodal plane at plane of symmetry **74**, **15** includes both the symmetric placement of transmitters **76** relative to plane of symmetry **74** and the antisymmetric operation of transmitters **76**.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made.

WHAT IS CLAIMED IS:

1. A probe, comprising:
 - (a) a sensor for determining a position of the probe; and
 - (b) a force field generator, disposed relative to said sensor so that there is a node of said force field substantially at said sensor.
2. The probe of claim 1, wherein said force field is oscillatory.
3. The probe of claim 2, wherein said force field is electromagnetic.
4. The probe of claim 2, wherein said force field is acoustic.
5. The probe of claim 1, wherein said force field is static.
6. The probe of claim 5, wherein said force field is electrical.
7. The probe of claim 5, wherein said force field is magnetic.
8. The probe of claim 1, further comprising:
 - (c) a housing whereto said sensor and said generator are rigidly attached.
9. The probe of claim 1, wherein said generator is disposed symmetrically relative to said sensor.

10. The probe of claim 1, wherein said generator includes a plurality of elements disposed symmetrically relative to said sensor.

11. A method for applying energy to a target, comprising the steps of:

- (a) providing a probe including:
 - (i) a sensor for determining a position of the probe, and
 - (ii) a force field generator, disposed relative to said sensor so that there is a node of said force field substantially at said sensor;
- (b) placing said probe in proximity to the target, with reference to at least one determination of said position of said probe made using said sensor; and
- (c) generating said force field, using said generator, the energy being applied to the target by an interaction of said force field with the target.

12. The method of claim 11, wherein said placing and said generating are effected substantially simultaneously.

13. A method for applying energy to a target, comprising the steps of:

- (a) providing a probe including:
 - (i) a sensor for determining a position of the probe, and
 - (ii) a force field generator including a plurality of elements;
- (b) placing said probe in proximity to the target, with reference to at least one determination of said position of said probe made using said sensor; and

(c) generating said force field, using said elements in a manner that produces a node of said force field substantially at said sensor, the energy being applied to the target by an interaction of said force field with the target.

14. The method of claim 13, wherein said placing and said generating are effected substantially simultaneously.

15. A probe comprising:

(a) a housing; and
(b) a force field generator, disposed so that there is a node of said force at least partially within said housing.

16. The probe of claim 15, wherein said force field generator is rigidly attached to said housing.

17. The probe of claim 15, wherein said housing has an element of symmetry and wherein said force field generator is disposed so that at least a portion of said node is substantially coincident with said element of symmetry.

18. The probe of claim 15, wherein said housing has an element of symmetry and wherein said force field generator includes a plurality of elements positioned symmetrically relative to said element of symmetry.

19. The probe of claim 15, further comprising:
 - (c) a sensor located substantially at said node.
20. A method for applying energy to a target, comprising the steps of:
 - (a) providing a probe including: a force field generator;
 - (b) placing said probe in proximity to the target; and
 - (c) generating said force field, using said generator, in a manner that applies the energy to the target, said force field having a node at least partially within said probe.
21. The method of claim 20, wherein said probe includes a sensor located substantially at said node.
22. The method of claim 21, wherein said sensor is operative to determine a position of said probe, and wherein said placing of said probe in said proximity to the target is effected with reference to at least one determination of said position of said probe made using said sensor.
23. A probe, comprising:
 - (a) a force field generator; and
 - (b) a sensor for producing a signal, said signal being subject to perturbation by said force field, said force field generator being disposed so as to minimize said perturbation.

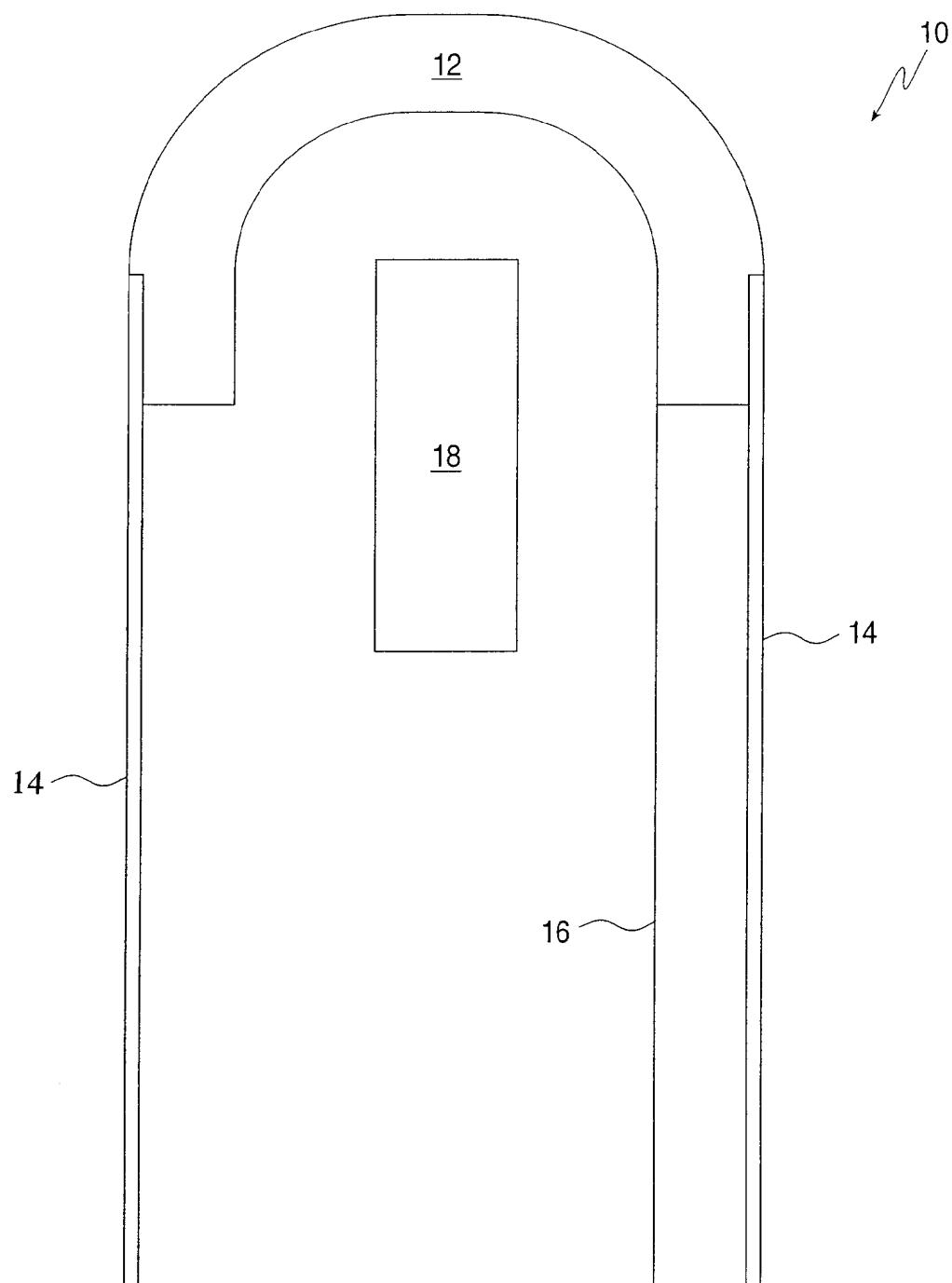
24. The probe of claim 23, wherein said force field has a node at least partially within the probe, said sensor being located substantially at said node.

25. The probe of claim 23, wherein said signal is representative of a position of the probe.

26. A method for applying energy to a target, comprising the steps of:
- (a) providing a probe including:
 - (i) a force field generator, and
 - (ii) a sensor for producing a signal, said signal being subject to perturbation by said force field, said force field generator being disposed so as to minimize said perturbation;
 - (b) placing said probe in proximity to the target; and
 - (c) generating said force field, using said generator, in a manner that applies the energy to the target.

27. The method of claim 26, wherein said signal is representative of a position of the probe, and wherein said placing of said probe in said proximity to the target is effected with reference to said signal.

1/6

**FIG.1 (PRIOR ART)****SUBSTITUTE SHEET (RULE26)**

2/6

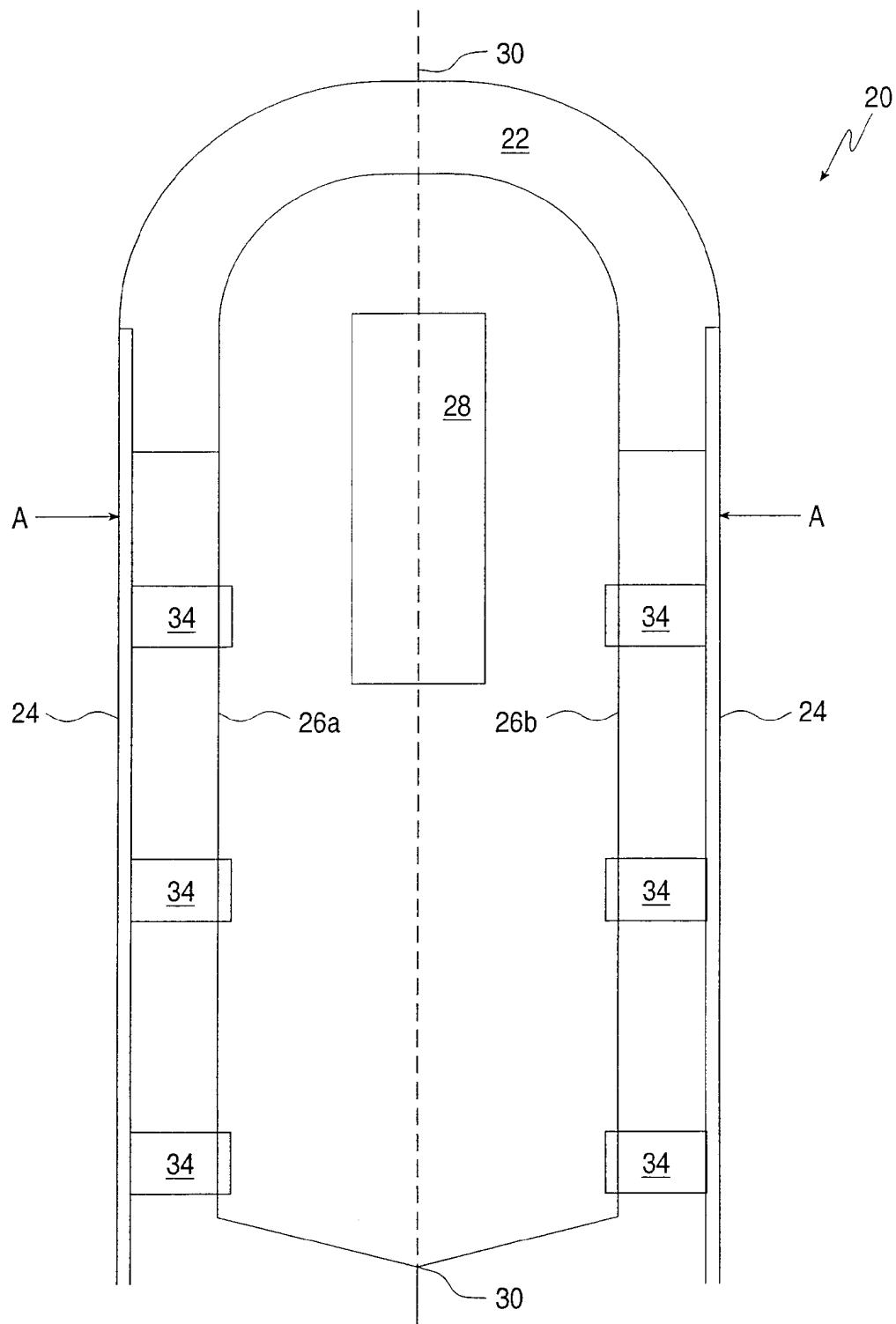


FIG.2

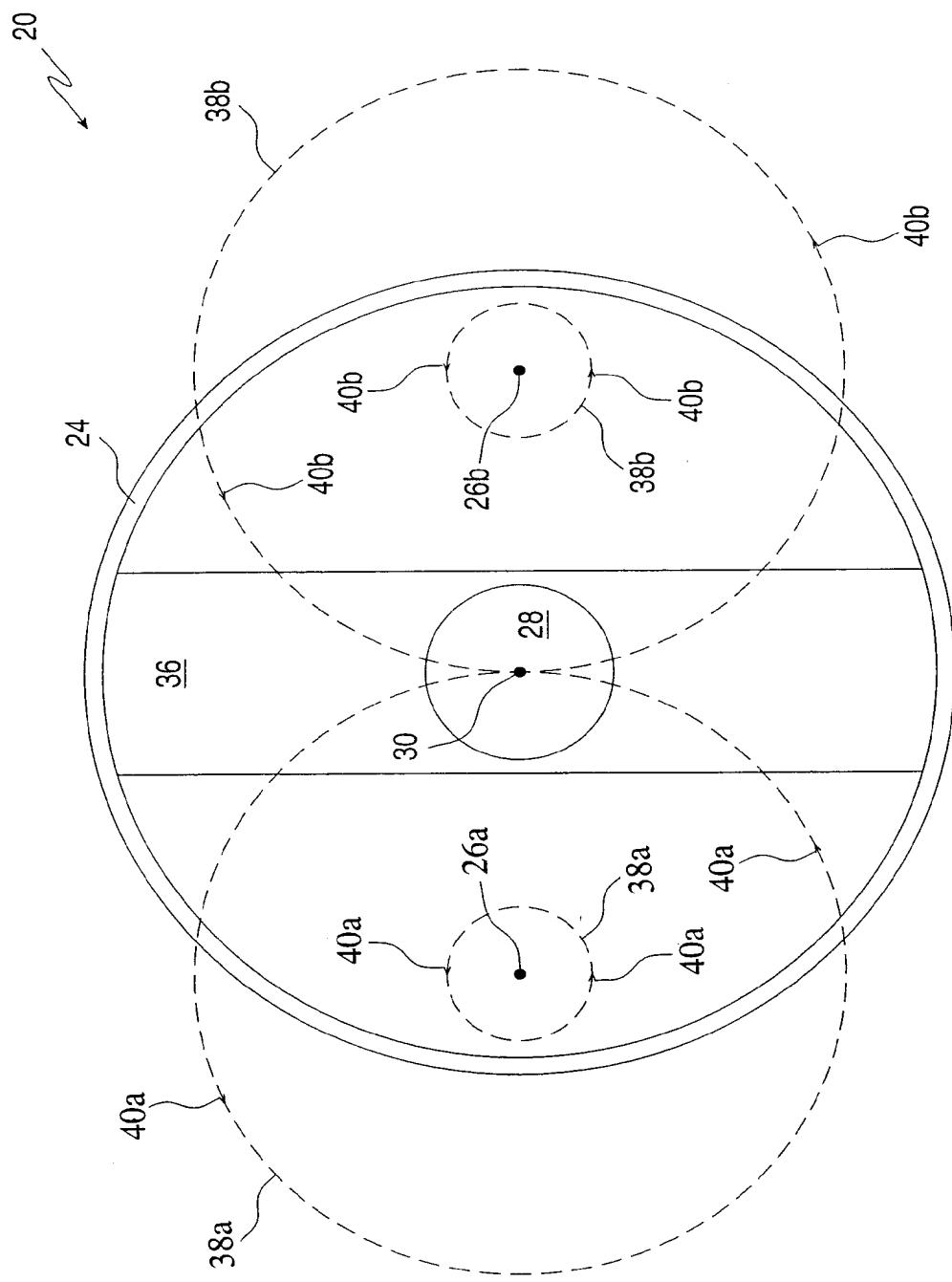


FIG.3

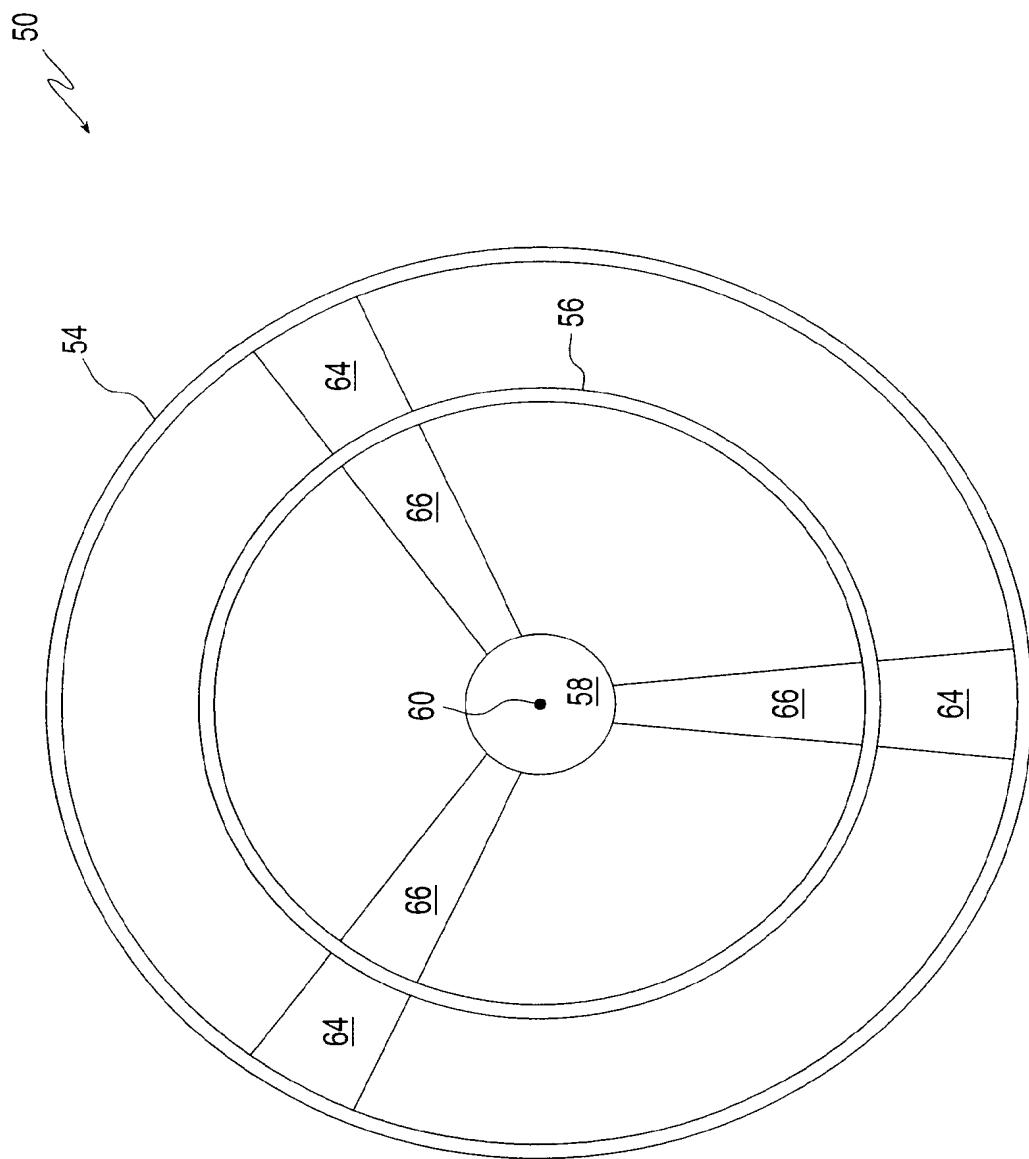


FIG.4

5/6

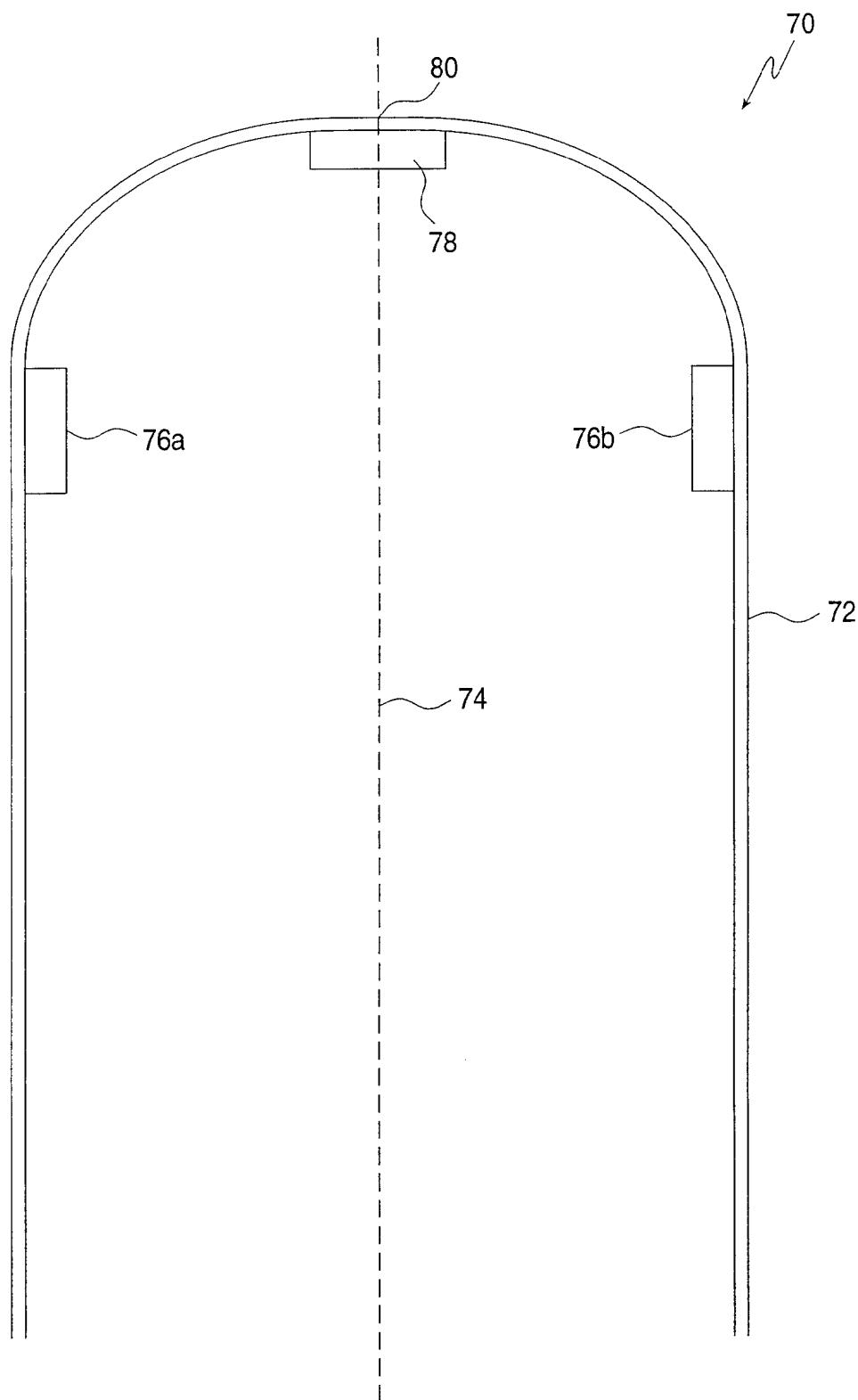


FIG.5

6/6

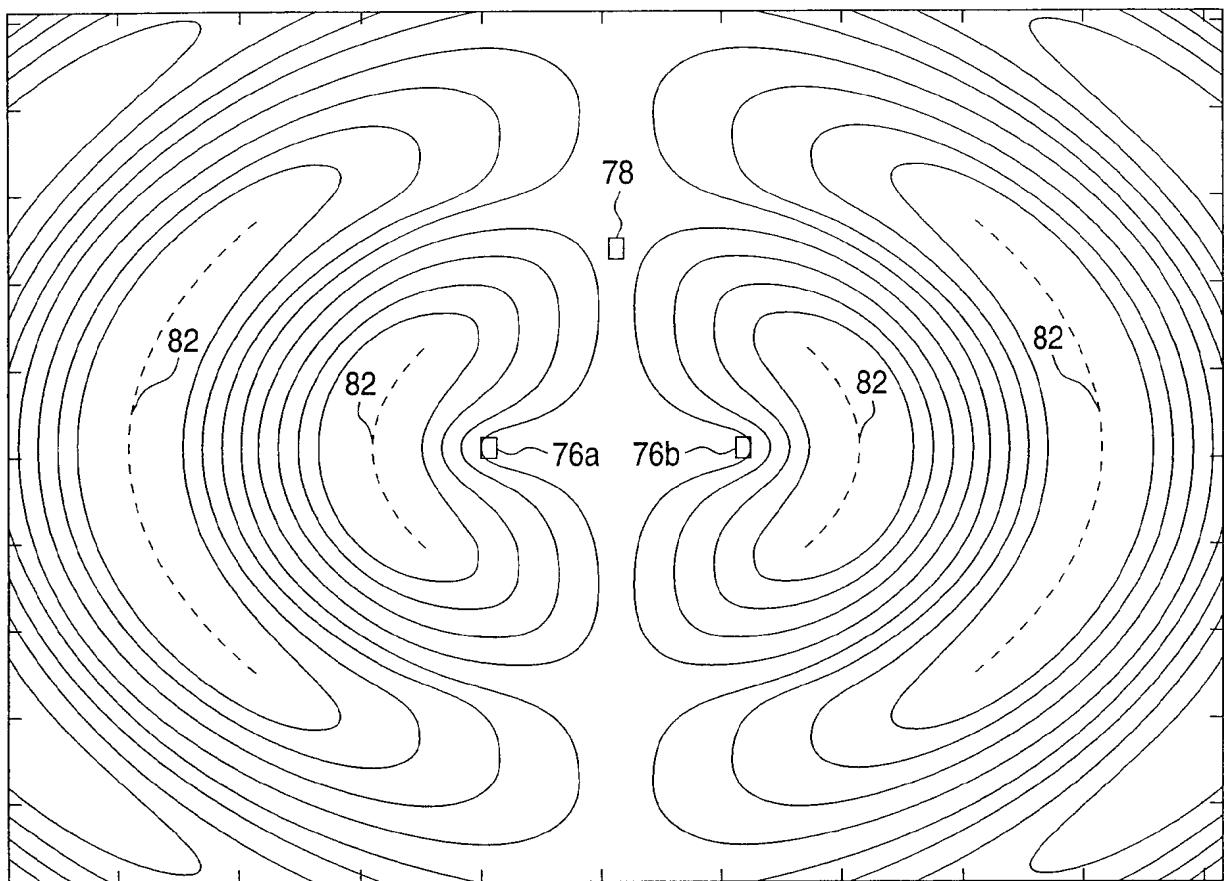


FIG.6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/26322

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 08/00

US CL : 600/462

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/462

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,606,975 A (Liang et al.) 04 March 1997, see entire document.	1-27
X	US 6,106,517 A (Zupkas) 22 August 2000, see entire document.	1-27

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
05 NOVEMBER 2000

Date of mailing of the international search report
28 NOV 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703) 305-3230

Authorized officer
MAULIN PATEL
Telephone No. (703) 305-6933